Original Article

Efficacy of Ozurdex implant in treatment of noninfectious intermediate uveitis

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Aims: To report our experiences using Ozurdex, a biodegradable implant, containing 0.7 mg of dexamethasone in the treatment of noninfectious intermediate uveitis. **Settings and Design:** Retrospective study design. **Methods:** We conducted a retrospective study of medical records of patients with noninfectious intermediate uveitis having either cystoid macular edema (CME) or vitritis who were not responsive to standard treatment and subsequently received Ozurdex implant from March 2011 to April 2013. The outcomes measured were best-corrected visual acuity, central retinal thickness (CRT), and vitreous haze score. **Statistical Analysis Used:** Paired *t*-test was used to test the significance of difference between quantitative variables. A $P < 0.05$ is taken to denote significant relationship. **Results:** Twenty eyes of 15 patients with mean age of 39.8 years who received Ozurdex implant were included in the study. The mean baseline visual acuity improved from 0. 666 logarithm of the minimum angle of resolution (logMAR) units to 0.479 logMAR units at 6 weeks after the implant. The mean CRT improved from 536.1 to 361.4 microns at 6 weeks postimplant both parameters were statistically significant. The ocular inflammation was controlled in almost all the patients. Cataract and raised intraocular pressure were documented complications. **Conclusion:** Ozurdex implant is a promising treatment option and efficient in controlling the inflammation and CME in cases of noninfectious intermediate uveitis not responding to standard treatment.

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Ozurdex is a biodegradable intravitreal dexamethasone implant approved by the United States Food and Drug Administration for treatment of macular edema associated with central retinal vein occlusion (CRVO) and for treatment of noninfectious posterior uveitis.[1-4] Previous studies demonstrated that dexamethasone, biodegradable implant (Ozurdex; Dexamethasone Intravitreal Implant 0.7 mg Allergan Inc., Irvine, CA, USA), can improve the visual acuity and macular thickness in a variety of causes including uveitis.[5] In this study, we describe our experience with dexamethasone implant in the treatment of noninfectious intermediate uveitis.

Methods

This is a retrospective study of the medical records of the patients who were treated in our hospital for noninfectious intermediate uveitis with Ozurdex implant from March 2011 to June 2013. All the patients were treated by a single uveitis specialist. The outcomes analyzed were best-corrected visual acuity (BCVA) which was measured with Snellen visual acuity charts converted to logarithm of the minimum angle of resolution (logMAR) units for statistical purpose, vitreous haze score graded according to Sun Working Group grading and central retinal thickness (CRT) assessed by optical coherence tomography (Cirrus OCT model no. 4000). Exclusion criteria include all the patients who had infectious uveitis or had any intraocular procedure within 6 months of the implant or had macular edema due to any other cause other than uveitis (e.g., diabetes, CRVO, etc.). The outcomes were analyzed at presentation, 6 weeks, 6 months, and the last visit within the 1 year period after the implant, respectively.

Ozurdex (700 µg, Allergan, Inc., Irvine, CA) was administered in accordance with the manufacturer's guidelines using the 22-gauge applicator device under aseptic conditions in the operation theater. Data analysis was done with the help of a computer using SPSS version 14.0, Chicago, IL, USA. Paired *t*-test was used to test the significance of difference between quantitative variables. A $P < 0.05$ is taken to denote significant relationship.

Results

A total of 20 eyes of 15 patients were included in the study. The baseline patient characteristics in this study were shown in Table 1. The percentage of males and females in our study are 53.34% and 46.66%, respectively. The mean age group of patients who received Ozurdex implant during the study period was 39.8 years (range 7–59 years). The standard treatment which was given includes oral steroids and immunosuppressants. Most common immnunosuppressants used were methotrexate and mycophenolate mofetil. After 3 months of the standard treatment, uveitis is considered persistent and not responding.

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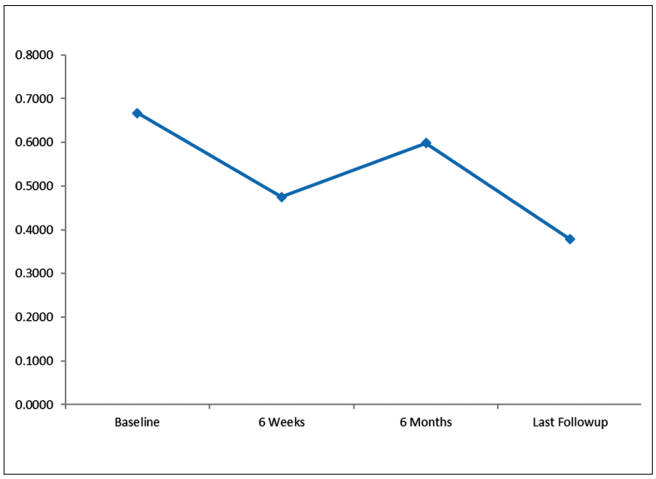
The mean baseline visual acuity improved from 0.666 to 0.479 logMAR units at 6 weeks after the implant, which was statistically significant. The trend of mean BCVA at each follow-up is represented in Graph 1. The mean CRT improved from 536.1 to 361.4 microns at 6 weeks postimplant which is statistically significant [Figs. 1 and 2]. The trend of mean CRT at each follow-up is represented in Graph 2. The percentage of eyes attaining a vitreous haze score of zero postimplant was 60%, 45%, 30% at each follow-up, respectively [Table 2]. It was found that 25% (5 eyes) required cataract surgery within 1 year period (within an average period of 6–8 months) postimplant. Two eyes (10%) required cataract surgery within 6 months period after the implant. However, one patient (1 eye) out of them had undergone the surgery after 6 months. Fifteen percent of eyes (3 eyes) developed intraocular pressure (IOP) >21 mmHg at 6 weeks follow-up postimplant. Two eyes had IOP ≥ 25 mm of Hg, out of which 1 eye was steroid responder. All eyes were medically managed for ocular hypertension thereafter. One eye diagnosed as pars planitis required vitrectomy to clear the severe vitreous opacities in the study period at 8 months postimplant. No other complications such as endophthalmitis and retinal detachment were noted.

Table 1: Patient baseline characteristics

	n	Percentage
Sex		
Male	8	53.3
Female	7	46.6
Age (years)		
Mean	39.8	
Range	7-59	
Mean BCVA	0.666 logMAR units	
Mean CRT	536.1 microns	
Number of phakic eyes	20	100
Number of eyes having epiretinal membrane at presentation	2	10

BCVA: Best-corrected visual acuity, CRT: Central retinal thickness, logMAR: Logarithm of the minimum angle of resolution



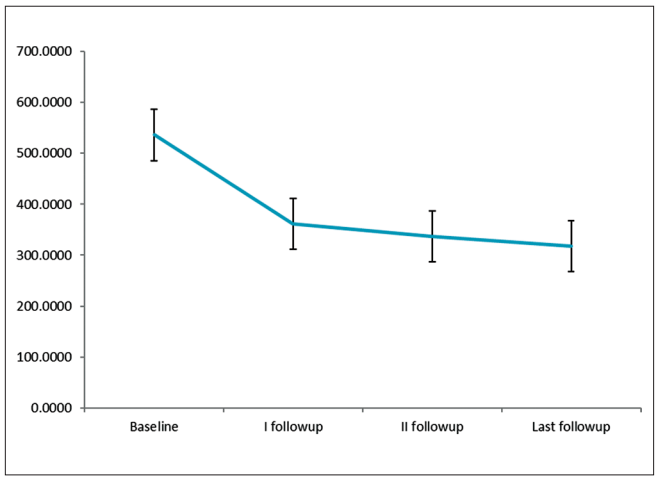
Graph 1: The trend of mean best-corrected visual acuity at each follow-up

Discussion

Corticosteroids have remained the mainstay of treatment in noninfectious intermediate uveitis since many decades. Cystoid macular edema (CME) secondary to uveitis is difficult to treat and may persist despite multiple interventions.[6]

The mean BCVA in our study had significantly improved at 6 weeks and final follow-up compared to the baseline; though there is improvement during the second follow-up, the difference is not statistically significant. This could be explained by the development of cataract to certain extent. A study by Zarranz-Ventura *et al*. has shown similar improvement of BCVA at their 1 month follow-up.[7] Two eyes (10%) required cataract surgery within 6 months postimplant. Similar incidence of cataract surgery was noted in other studies.[4,8] However, within 1 year follow-up a total of 5 eyes required cataract surgery. This can be probably explained by a longer follow-up period in our study comparatively. The mean CRT in our study has shown statistically significant improvement at each follow-up compared to the baseline reading, and the improvement has been maintained up to our last follow-up though maximum improvement has occurred within the 6 weeks of the implant. The study by Cao *et al*.[8] and Adán *et al*.[9] has shown similar response with Ozurdex implant in regards to CME at their follow-ups, respectively. Fifteen percent of the eyes developed raised IOP in our study comparable to the other studies.[8] It was found that the 2 eyes which had epiretinal membrane (ERM) at presentation had minimal improvement in CRT. A recent study demonstrated that the presence of an ERM may limit the response to medical therapy in uveitic CME.[10] The maximum efficacy of the drug is found to be at 1–2 months postimplantation.

This is the first Indian study analyzing the efficacy of Ozurdex implant in noninfectious intermediate uveitis to the best of our knowledge. Most of the current literature studied its effects for short period (usually 6 months); there was limited data over long-term effects on consistency of its efficacy after a single implant. The present study demonstrates the outcomes of a single injection Ozurdex and estimates chances of attaining sustainable results. The current analysis studied the consistency of the effects of Ozurdex over 52 weeks. There was sharp



Graph 2: The trend of mean central retinal thickness at each follow-up

Table 2: BCVA, CRT, and vitreous haze at baseline and final visit

Baseline vision BCVA	BCVA last visit	CRT baseline thickness (μm)	CRT last visit (μm)	Vitreous haze baseline	Vitreous haze last visit
0.48	0.18	684	440	1.5	0.5
0.48	0.1	485	258	1	0.5
0.78	0.5	636	163	2	0.5
1.78	1.48	688	620	1	0.5
0.78	0.3	771	140	2	0
0.78	0.18	476	280	1	0.5
0	0.18	572	641	1.5	0
0.3	0.3	294	640	2	0.5
1.3	1.3	377	308	1	0
1.78	1	779	492	2	0.5
0.3	0.18	160	159	3	1
0.78	0.18	408	155	0.5	0
0.4	0.3	579	524	1.5	1
0.3	0.18	546	340	1.5	0
0.5	0.18	760	212	2	1
0.78	0.48	764	314	2	1
0.3	0	654	169	1	0
0.48	0	589	289	1.5	0.5
0.18	0.18	320	342	1.5	0.5
0.48	0.3	180	212	2	1

BCVA: Best-corrected visual acuity, CRT: Central retinal thickness

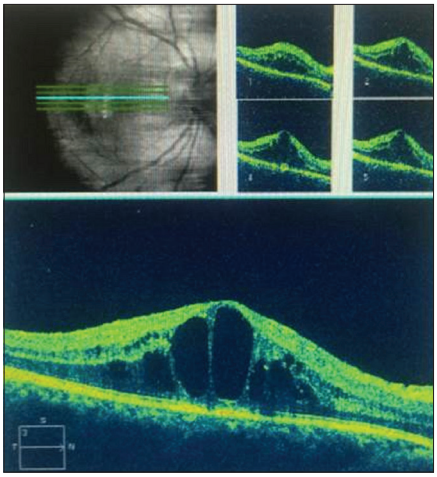


Figure 1: Optical coherence tomography of the patient before treatment with Ozurdex implant

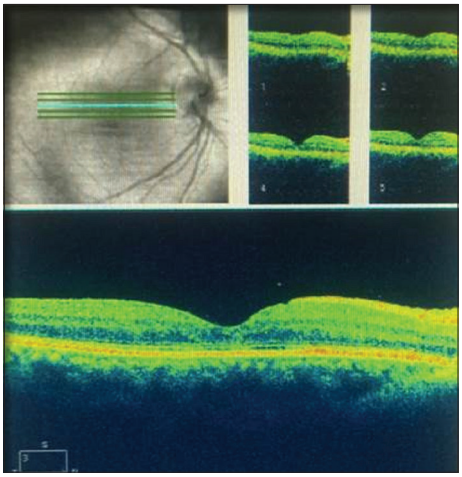


Figure 2: Optical coherence tomography of the patient after treatment with Ozurdex implant

reduction in CRT and concomitant gain in the visual acuity in the first 6–8 weeks after which improvement in CRT was statistically significant until the end of 1 year though about 40% of eyes had CRT >300 microns. There was progression of cataract in later half of the study but had no detrimental effect on final BCVA.

The main limitations of this study are that it has a retrospective study design. The study cohort was small to comment, especially with respect to its effect on consistent maintenance of the CRT. Progression of cataract cannot be explained solely on the effects of Ozurdex implant because many patients had been treated before with local steroids.

Conclusion

This study was consistent with the safety profiles in previously published studies. Dexamethasone implant is particularly useful in persistent chronic CME and vitritis due to noninfectious intermediate uveitis. It has higher safety profile and long duration of action for an average of 4–6 months. Long-term follow-up studies are yet required to assess its side effects mainly cataract and raised IOPs and the need for repeat injections.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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